

**Subject:** FW: [Iccvam-all] ICCVAM Request for Information on Alternative Skin Sensitization Methods and Comment on Proposed Activities

**Date:** Monday, December 9, 2013 5:14:04 AM Eastern Standard Time

**From:** Sakaguchi Hitoshi (坂口 斉)

**To:** NIEHS NICEATM

**CC:** Takenouchi Osamu (竹之内 修), Miyazawa Masaaki (宮澤 正明), 足利 太可雄  
[REDACTED]

Dear Dr. Catherine Sprinkle,

We have developed an in vitro skin sensitization test named human Cell Line Activation Test (h-CLAT). Recently we noticed that ICCVAM and NICEATM required information and comments for your activity. Previously we already have communicated with ICCVAM for our h-LCAT and sent some our data. Recently we had a new manuscript and got additional data, so we would like to send you two files as useful information.

The PDF file is the latest manuscript of the h-CLAT.  
In this paper, we verified the predictivity for low water-soluble chemicals.  
It will be helpful to discuss the applicability domain of in vitro tests.  
In addition, the excel file is unpublished dataset of the h-CLAT.  
Please use the dataset for evaluation of the h-CLAT.

If you have any question and comment, please let me know.

Best regards,

Hitoshi Sakaguchi, Kao Corporation  
Takao Ashikaga, Shiseido Co., Ltd

-----Original Message-----

From: [iccvam-all@list.niehs.nih.gov](mailto:iccvam-all@list.niehs.nih.gov) [<mailto:iccvam-all@list.niehs.nih.gov>]

Sent: Wednesday, November 13, 2013 8:55 PM

To: [iccvam-all@list.niehs.nih.gov](mailto:iccvam-all@list.niehs.nih.gov)

Subject: [Iccvam-all] ICCVAM Request for Information on Alternative Skin Sensitization Methods and Comment on Proposed Activities

ICCVAM is developing a plan of action to advance alternative test methods and testing strategies for skin sensitization. As part of this process, ICCVAM is interested in receiving information on the state of the science of test methods and testing strategies for skin sensitization and about activities in this area of which ICCVAM may not be aware. ICCVAM requests this information in an announcement published in today's Federal Register.

The notice is available at  
<http://ntp.niehs.nih.gov/iccvam/SuppDocs/FedDocs/FR/FR-2013-27095.pdf>.

Activities ICCVAM is considering include: organizing workshops; developing guidance documents; collaborating with international organizations that are conducting relevant validation studies or preparing relevant guidance; providing support to NICEATM's efforts in this area; and providing information about funding resources and agency priorities to test method developers. ICCVAM invites its stakeholders to consider these proposed activities and provide comment on the following:

--The role ICCVAM should play in the development and evaluation of alternative skin sensitization test methods and testing strategies --The potential contributions that regulated industries or nongovernment organizations and

other interested parties might make toward these efforts

Please submit comments and information in response to this request by December 9, 2013. Submission of comments via email to [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov) <<mailto:niceatm@niehs.nih.gov>> is preferred. With your comment, please include your name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any).

Responses received will be posted on the NTP website at <http://ntp.niehs.nih.gov/go/40498> and identified by name and affiliation or sponsoring organization if provided. Please do not include any proprietary, classified, confidential, or sensitive information in responses.

ICCVAM will also request comment from the OECD and from partners in the International Cooperation on Alternative Test Methods. ICCVAM will then consider all comments as it develops plans to augment and support activities that will advance the state of the science for alternative skin sensitization test methods and testing strategies.

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Catherine Sprankle

Sr. Communications Specialist

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